IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES *ex. rel.* RUSS & MURPHY Plaintiffs, v. NORTH AMERICAN RESCUE, *et al.*, Defendants.	: : : : : : : :	Civil Action No. 21-CV-4238 **ORAL ARGUMENT REQUESTED**

C-A-T RESOURCES, LLC'S
BRIEF IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Relators Corey Russ and Chris Murphy fail to state a FCA claim against C-A-T Resources, LLC ("CR"). Count One fails to allege: (1) a false statement or that CR misrepresented compliance with a statutory, regulatory, or contractual requirement; or (2) that the Government consistently refuses to pay claims based on National Stock Numbers ("NSNs") when the Government has evaluated and endorsed an "item of supply" substitution or modification. Count Two fails because there are no well-pled facts that could plausibly show the CAT is made in China. And Relators have pled themselves into the public disclosure bar in both counts.

Relators are not whistleblowers with inside knowledge of fraud against the Government. Relators are CR's competitors, whose efforts to develop a tourniquet to replace the Combat Application Tourniquet ("CAT") as "the approved primary tourniquet to be issued to soldiers" were unsuccessful. Relators are trying to use the FCA as a means of financial retribution.

In head-to-head competition conducted by the Government "in an effort to evaluate the current offering of commercially available tourniquets,"[1] relators' tourniquet—the Tactical Mechanical Tourniquet ("TMT")—consistently finished behind the CAT. During arm application, the TMT's "locking clip broke" as the result of a "defect in the molded plastic locking mechanism."[2] "Many participants had difficulty" with the TMT, "often struggl[ing] to secure the windlass into the locking clip."[3] After specifically testing the CAT Gen 7 against the TMT, the Government "reaffirmed" the CAT "as the chosen extremity tourniquet."

[1] R. Dory, MS, J. Bequette, RN, D. Cox, Naval Med. Research Unit San Antonio, Evaluation of Extremity Tourniquet Designs During Self-Application in the Hands of Military Service Members, NAMRU-SA Report No. 2017-54 (Mar. 2017) Ex. 1 at 6.
[2] *Id.* at 17.
[3] *Id.* at 18-19.

Prior patent litigation frustrated relators' ability to profit from the TMT. Relators' earlier lawsuit against the Government and efforts to undermine the DoD's endorsement of the CAT Gen 7 to the exclusion of the TMT failed. Relators' efforts to gain traction with the FBI regarding the CAT Gen 7 failed.

This is relators' latest attempt to undermine the CAT and CR, and it fails on its face. With full knowledge—and endorsement—of the CAT Gen 7, the Government did not assign it a separate NSN. That is unsurprising, since the Government has used the same "item of supply" NSN for every CAT generation since 2004. NSN 6515-01-521-7976 is undisputedly *not* unique to the CAT Gen 7, and as government procurement experts in all things NSN-related, relators either knew or should have known that. Relators' inability to allege materiality and their admission of prior public disclosure of the same allegations in the FAC are separately fatal to their "improper substitution" claims.

Relators' Berry Amendment/TAA allegations are even more implausible. Relators' allegation is that the CAT must be made in China, but the only "particular details" are CR's shipping labels reflecting an 11-digit CR "Supplier Item Number" and the initials "BMA" under "Packed By." According to relators, "CR" must mean Chinese "Customs Registration," and "BMA" must mean "Bahamas Maritime Authority." But that would also mean that CR—in an attempt to "disguise" the CAT's "Chinese origin"—shipped boxes made in North Carolina to either China or the Bahamas with pre-printed labels displaying Chinese origin.

Regardless, Customs Registration numbers have ten digits, not 11. And as a matter of judicial experience and common sense, three initials on a shipping label are "insufficient factual matter" to support a presumption of truth to relators' contention that CR's boxes were repacked in

the Bahamas with Chinese-made CATs, instead of packed by an CR employee named Ben M. Adair in South Carolina.

Relators' conclusory allegation that the CAT is Chinese-made is insufficient, and without well-pleaded facts that could plausibly show the CAT is made in China, Count Two fails to allege false certification of compliance with the Berry Amendment and TAA. The FAC should be dismissed.

BACKGROUND

I. *CRI v. Combat Medical*

The Combat Application Tourniquet (the "CAT") was conceived in 2003 by special forces medic Mark Esposito. *Composite Res., Inc. v. Combat Med. Sys., LLC*, No. 3:17-CV-72-MOC-DSC, 2020 WL 7365316, at *1 (W.D.N.C. Dec. 15, 2020) ("*CRI v. Combat Medical*"). Esposito patented the technology embodied in the CAT and later sold the CAT patent to Composite Resources, Inc. ("CRI"), which developed the process and capability for mass-producing the CAT from prototype to today. *Id*.

In February 2017, CRI filed a patent infringement case asserting that the Tactical Mechanical Tourniquet ("TMT") manufactured by Alphapointe and distributed by Combat Medical Systems, LLC ("Combat Medical")[4] infringed CRI's CAT patent. *Id*., at *1, 7. Combat Medical argued that the TMT did not infringe the CAT patent and, further, that the CAT patent was invalid. *Id*., at *1.

In December 2020, the court found that the CAT patent was not invalid, but that the TMT did not infringe the CAT patent. *Id*. However, due in part to the litigation, Combat Medical was

[4] Relator Russ "founded" Combat Medical Systems, LLC ("Combat Medical"), and Relator Murphy "worked at Combat Medical." FAC ¶¶ 2, 3. Kutak Rock represented Combat Medical in No. 3:17-CV-72-MOC-DSC, *Composite Res., Inc. v. Combat Med. Sys., LLC*, in the United States District Court for the Western District of North Carolina.

prevented from selling the TMT to the Department of Defense ("DoD") for four years. *Composite Res. v. Combat Med. Sys., LLC*, No. 3:17-cv-00072-MOC-DSC, 2021 WL 1669038, at *2 (W.D.N.C. Apr. 28, 2021).

II. *Combat Medical v. Esper*

During the pendency of *CRI v. Combat Medical*, on December 23, 2019, Combat Medical filed suit against the U.S. Army Medical Material Agency ("USAMMA") over the TMT. *Combat Med., LLC v. Esper*, No. 1:19-cv-1609, 2020 WL 2115447, at *1 (E.D. Va. May 4, 2020) ("*Combat Medical v. Esper*"). Combat Medical alleged that because of decisions made by the USAMMA, Combat Medical had been prevented from selling the TMT to any agency within the DoD. *Id*. Relator Corey Russ verified and Kutak Rock certified the complaint in *Combat Medical v. Esper*.[5]

Combat Medical alleged that in March 2005, the Army Surgeon General selected the third-generation CAT (the "CAT Gen 3") sold by NAR as the approved primary tourniquet to be issued to soldiers as part of the Individual First Aid Kit ("IFAK"). *Id*. at *2. The *Esper* court noted: "NAR is one of Combat Medical's competitors." *Id*. at *2 n.4.

Combat Medical further alleged in Esper that in 2010, the DoD established a Tourniquet Working Group to develop standards for the safety, efficacy, and physical requirements of extremity tourniquets and evaluated tourniquets based on those requirements through a series of tests called the Joint Operational Evaluation of Field Tourniquets ("JOEFT"). *Id*., at *2. The JOEFT testing began with 13 different tourniquets and was conducted in four phases. *Id*. By the final phase in 2017, the three highest rated tourniquets remained in the JOEFT, including the seventh-generation CAT (the "CAT Gen 7") and the TMT. *Id*.

[5] No. 1:19-cv-01609-TSE-JFA, *Combat Medical, LLC v. Esper*, Doc. 1 (12/23/19).

On September 3, 2017, the final JOEFT test report was issued. *Id*. The report stated that (i) the CAT achieved the highest combined success rate across arm and leg applications, (ii) the CAT had the shortest application times, and (iii) the CAT was ranked as the most preferred tourniquet design by the test subjects. *Id*.[6]

Combat Medical further alleged in *Esper* that on September 19, 2018, the USAMMA, an agency within the U.S. Army Medical Research and Material Command, issued Medical Material Quality Control Message ("MMQC") 18-2324. *Id*. MMQC-18-2324 "inform[ed] all Army units that the Combat Application Tourniquet (CAT) is the chosen tourniquet for the U.S. Army in order to ensure our soldiers receive the best possible medical care." *Id*. MMQC-18-2324 further stated that: "The U.S. Army has completed extensive testing based on defined requirements to determine the extremity tourniquet which best meets the needs of the warfighter. The combat application tourniquet (cat) has met or exceeded all defined requirements, was the superior performer, and was reaffirmed as the chosen extremity tourniquet." In *Esper*, Combat Medical acknowledged these comments in MMQC-18-2324 referred to the "CAT Gen 7."[7]

MMQC-18-2324 further provided that "[a]ny resupply kit previously procured that does not have the [CAT] must be canceled and the appropriate resupply kit procured, due to the inherent safety risk of an unauthorized tourniquet." *Id*., at *3 (quoting MMQC-18-2324). MMQC-18-2324 further directed Army units to work with the USAMMA and the Defense Logistics Agency ("DLA") "to stop the procurement of two specific first aid kits identified by their National Stock Numbers ('NSN')." *Id*. (same). Both first aid kits identified in MMQC-18-2324 were

[6] The court noted that while Combat Medical had not attached the JOEFT test report to the complaint, the complaint referenced the final JOEFT test report multiple times and neither party disputed the report's authenticity. Accordingly, the court considered the final JOEFT test report in adjudicating defendants' motion to dismiss. *See Combat Med., LLC v. Esper*, No. 1:19-CV-1609, 2020 WL 2115447, at *4 n.5 (E.D. Va. May 4, 2020).

[7] No. 1:19-cv-01609-TSE-JFA, *Combat Medical, LLC v. Esper*, Doc. 1 ¶¶ 27, 34, 58, 96 (12/23/19).

manufactured by Combat Medical and contained the TMT. *Id*. The MMQC-18-2324 states that these kits "have a tourniquet in them that is not approved for Army use or procurement." *Id*. (quoting MMQC-18-2324).

In *Esper*, Combat Medical, through a pleading verified by relator Russ, alleged that the MMQC-18-2324 had caused the cancellation of orders for the TMT and effectively barred Combat Medical from selling tourniquets to the Army. *Id*. Combat Medical further alleged that because of MMQC-18-2324, TMT's NSN was canceled, and that without an active NSN, Combat Medical was effectively barred from selling the TMT to any DoD purchaser. *Id*.

On May 4, 2020, the court dismissed Combat Medical's claims for want of jurisdiction, holding that Combat Medical's NSN-related claims had been brought "in connection with a procurement or proposed procurement." *Id*., at *6. Therefore, Combat Medical's claims were within the exclusive jurisdiction of the Court of Federal Claims. *Id*.

III. The Instant Qui Tam Action

On September 24, 2021, qui tam Relators Russ (Combat Medical's "founder") and Murphy (who "worked at" Combat Medical) filed this False Claims Act case alleging two counts against CR: (1) "Unlawful Substitution of the CAT Gen 7 for the CAT Gen 6," and (2) "False Certification of Compliance with Berry Amendment and TAA." Relators omit their history as competitors of the CAT and the procedural history of their litigation relating to the TMT.

Relators also omit highly relevant facts from the FAC. Relators base their "unlawful substitution" claim on MMQC-16-1284, which they characterize as "highlight[ing] Defendants' derogation of basic principles of Government logistics practice" and "reflect[ing] DoD's recognition that the CAT Gen 7 is unsafe and prone to failure." FAC ¶ 69, 86. Relators omit that—

as stated in their *Esper* complaint (verified by Russ under penalty of perjury and certified by Kutak Rock)—*subsequent to MMQC-16-1284*—the Government and DoD have:

1. "declar[ed] ***the CAT Gen 7*** 'the only army approved individual soldier tourniquet'" (emphasis added);

2. "***re***affirmed" the ***CAT Gen 7*** "as the chosen extremity tourniquet" (emphasis added);

3. "endorsed the ***CAT Gen 7*** as the 'only army approved individual soldier tourniquet for individual carry'" (emphasis added); and

4. "recommended the use of … the ***CAT Gen 7***." (emphasis added).[8]

To be clear, these are relator Russ' own sworn characterizations of MMQC-18-2324, ALARACT 090/2018, and the CoTCCC's May 8, 2019 "revised tourniquet recommendations" specifically as to the CAT Gen 7, referenced in and attached by Kutak Rock to the *Esper* complaint. And these Government memoranda, decisions, and recommendations regarding the CAT Gen 7 post-date and supersede the MMQC upon which Relators base Count One. These highly relevant, opposite facts were omitted despite having been previously alleged in another federal complaint verified by Russ and certified by Kutak Rock.

STANDARD OF DECISION

The First Amended Complaint ("FAC") should be dismissed as to CR under 12(b)(6) for failure to state a claim, under Rule 9(b) for failing to meet the particularity requirement, and under the public disclosure bar. To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). The Court must accept as true all factual allegations in the complaint and make all reasonable inferences in favor of the non-moving party. Fed. R. Civ.

[8] No. 1:19-cv-01609-TSE-JFA, *Combat Medical, LLC v. Esper*, Doc. 1 ¶¶ 27, 34, 58, 96 (12/23/19).

P. 12(b)(6); *McDermott v. Clondalkin Group, Inc*., 649 Fed. Appx. 263, 266 (3d. Cir. 2016). "All relevant evidence and all reasonable inferences that can be drawn from the record are ... viewed in the light most favorable to the non-moving party." *United States ex rel. Travis v. Gilead Scis., Inc*., 596 F. Supp. 3d 522, 534–35 (E.D. Pa. 2022).

However, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010) (quoting *Twombly*, 550 U.S. at 556–57 (internal quotation marks omitted)); *QVC, Inc. v. Resultly, LLC*, 159 F. Supp. 3d 576, 583 (E.D. Pa. 2016). The plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." *United States ex rel. Ellsworth Assoc., LLP v. CVS Health Corp*., 660 F. Supp. 3d 381, 392 (E.D. Pa. 2023).

Because a claim under the FCA sounds in fraud, "False Claims Act plaintiffs must also plead their claims with plausibility and particularity under ... [Rule] 9(b)." *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 195; Fed. R. Civ. P. 9(b). "Rule 9(b)'s particularity requirement requires a plaintiff to allege 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.'" *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019) (citation omitted). For Relators to satisfy Rule 9(b)'s pleading requirement, "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quotation omitted); *United States ex rel. Travis v. Gilead Scis., Inc*., 596 F. Supp. 3d 522, 535 (E.D. Pa. 2022).

Generally, to state a claim under the FCA, a relator must allege facts sufficient to satisfy four elements: (1) a false statement or fraudulent course of conduct; (2) made knowingly (scienter); (3) that was material, (4) causing the Government to pay out money or forfeit moneys due. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 136 S.Ct. 1989, 195 L.Ed.2d 348 (2016) (materiality); *United States ex rel. Wilkins v. United Health Grp., Inc*., 659 F.3d 295, 302 (3d Cir. 2011) (falsity, causation, knowledge). Even so, if there is a qualifying "public disclosure" and the relator is not an "original source" such claims must be dismissed under 31 U.S.C. § 3730(e)(4). *United States ex rel. Ellsworth Assoc., LLP v. CVS Health Corp*., 660 F. Supp. 3d 381, 394 (E.D. Pa. 2023); *United States ex rel. Travis v. Gilead Scis., Inc*., 596 F. Supp. 3d 522, 536 (E.D. Pa. 2022).

ARGUMENT

Relevant here, the FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" (31 U.S.C. § 3729(a)(1)(A) (false presentment, Count One)); or "knowingly makes, uses, or causes to be [] used, a false record or statement material to a false or fraudulent claim" (id. § 3729(a)(1)(B) (false record, Count Two)). Relators have failed to state a claim for violation of any of the FCA sections.

I. Count One: "Unlawful Substitution of the CAT Gen 7 for the CAT Gen 6"

A. Relators have failed to allege that CR violated a statutory, regulatory, or contractual requirement, and thus their complaint fails to plead materiality.

The FAC fails to identify whether Relators are alleging Count One under a factually or legally false theory. Count One fails and should be dismissed under Rule 9(b) accordingly.

Regardless of which theory is alleged, the FAC fails to identify an underlying false statement or allege that CR misrepresented compliance with a statutory, regulatory, or contractual requirement. *See United States ex rel. Alejandro v. Philadelphia Vision Ctr*., No. CV 20-2027,

2022 WL 294548, at *5 (E.D. Pa. Feb. 1, 2022) ("For Alejandro's claims to proceed to discovery, she must allege Defendants misrepresented compliance with regulatory 'requirements that are so central to the provision of [optometric care] that the [Government] would not have paid [the submitted] claims had it known of these violations.'").

The only "statutory, regulatory, or contractual requirement"[9] arguably identified by Relators in Count One is "FLIS Technical Procedures, vol. 4, § 4.1.1(a)." FAC ¶ 76; Dep't of Def., Federal Logistics Information System: FLIS Technical Procedures, Item Identification § 4.1.1 (Aug. 2020). According to Relators, under section 4.1.1(a), each "'item of supply' purchased or maintained by Government agencies is associated with exactly one unique identifier (such as an NSN), and likewise each NSN is associated with exactly one item of supply." FAC ¶ 76. Relators contend that CR "violated this basic rule of Government procurement and logistics by intentionally marking CAT Gen 7 with the same NSN used to identify the CAT Gen 6 and by filling orders for the CAT Gen 6 with CAT Gen 7s." FAC ¶ 76.

CR has been unable to find a single case in which the Federal Logistics Information System ("FLIS") Technical Procedures have been alleged as the requisite "statutory, regulatory, or contractual requirement" for purposes of stating a FCA claim.[10] According to the Defense Technical Information Center, "[t]he FLIS is a *management system* designed to collect, store, process, and provide item related logistics information."[11] "It is the *catalog* of more than fifteen million Supply Items used by the United States Government and North Atlantic Treaty

[9] *See United States ex rel. Ellis v. CVS Health Corp.*, No. CV 16-1582, 2023 WL 3204015, at *4 (E.D. Pa. May 2, 2023) ("[I]t is not clear that any statutory, regulatory, or contractual requirements were violated.").
[10] In fact, a Westlaw Precision plain language search for "Federal Logistics Information System FLIS" returns no results.
[11] Defense Technical Information Center (last visited Feb. 23. 2024), https://apps.dtic.mil/sti/citations/ADA309941 (emphasis added).

Organization (NATO) partners."[12] CR has found nothing to suggest that the FLIS Technical Procedures constitute "statutory, regulatory, or contractual requirements."

Because Relators have not identified any contracts, regulations, or statutes that apply to their allegations as to Count One, they have failed to plead materiality, and their complaint is therefore deficient. *See, e.g.*, *United States ex rel. Pritzker v. Sodexho, Inc.*, 364 Fed. Appx. 787, 790 (3d Cir. 2010) (affirming the dismissal of the plaintiff's claim because the complaint did not "identify any regulation requiring competitive bidding"); *United States ex rel. Knisely v. Cintas Corp.*, 298 F.R.D. 229, 241 (E.D. Pa. 2014) (granting motion to dismiss because "without alleging which ... standards the federal agencies mandate, [the plaintiff's] generalization does not substantiate his claim that [the defendant's] payment claims under those contracts were false"); *see also United States ex rel. Ligai v. ESCO Techs., Inc.*, 611 Fed. Appx. 219, 220 (5th Cir. 2015) (upholding dismissal because the "complaint fail[ed] to identify any specific statute, regulation, or contract provision").

B. By ignoring the FLIS Technical Procedures' definition of "item of supply," relators fail to state a claim.

Section 4.1.1(a)(3) of the FLIS Technical Procedures—which appears to be what Relators are relying on for their "exactly one" standard—provides as follows:

> (3) Basic Principles of Item Identification:
>
> (a) Each item identification shall be applicable to one, and only one, *item of supply*.
>
> (b) Each *item of supply* shall have applicable to it one, and only one, item identification.

(Emphasis added). Section 4.1.1(a)(3) thus speaks in terms of "items of supply," not NSNs.

[12] *Defense Logistic Agency, Federal Logistics (FED LOG) Data, available at* https://media.defense.gov/2022/Mar/03/2002948694/-1/-1/1/220303-D-AA526-2250.PDF (emphasis added).

Section 3 of the APPENDIX 4-7-A to Volume 4 of the FLIS Technical Procedures, Item Identification—entitled "DEFINITIONS FOR CATALOGING PURPOSES"—defines "item of supply" in subsection 3.2:

> Item of Supply — [An NSN which describes] a single item of production, *two or more items of production that are functionally interchangeable or that may be substituted for the same purpose and are comparable in terms of use,...or a modification of a normal item of production*. (Emphasis added).

Assuming for the sake of argument that Section 4.1.1(a) constitutes a "statutory, regulatory, or contractual requirement," the FLIS Technical Procedures for Item Identification expressly contemplate that an item of supply which has been assigned a NSN can include "two or more items that": (1) "are functionally interchangeable," or (2) "may be substituted for the same purpose and are comparable in terms of use." Relevantly here, the FLIS Technical Procedures for Item Identification further contemplate that an item of supply which has been assigned an NSN can include "a modification of a normal item of production." Accordingly, while Relators are correct that each item of supply is assigned an NSN, Relators omit the broader definition of "item of supply," which clearly encompasses both the Gen 6 and Gen 7 CAT.

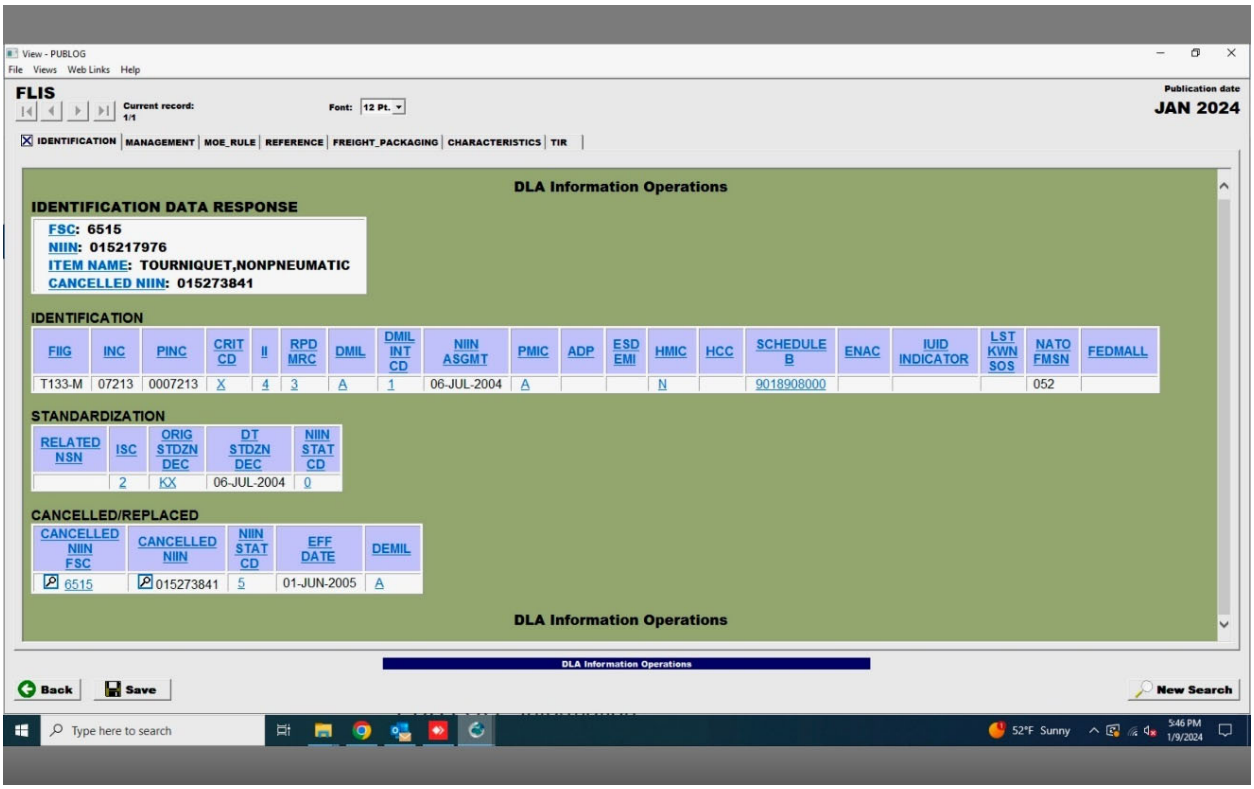
CR did not—"by using the same NSN for both the CAT Gen 6 and CAT Gen 7"—"knowingly misrepresent" the CAT Gen 7 as being "*precisely the same product* as the CAT Gen 6." FAC ¶ 168. At most, CR represented that the CAT Gen 7 "may be substituted for," or was "functionally interchangeable" with, "comparable" to, or "a modification of" the CAT Gen 6. Relators do not allege that the CAT Gen 7 is not functionally interchangeable with the CAT Gen 6, nor do they allege that the CAT Gen 7 may not be substituted for the CAT Gen 6. Relators do not allege that the CAT Gen 7 is not comparable to or a modification of the CAT Gen 7. Nor would of these allegations pass the plausibility standard. Accordingly, Count One should be dismissed as to CR.

C. As a matter of public record, NSN 6515-01-521-7976 is not "unique" to the CAT Gen 6.

As demonstrated by the *Esper* matter, Relators are well-steeped in all matters NSN. Relators purport to be "the original sources of the information" in the FCA, and to have particularized knowledge of "Government procurement and logistics." FAC ¶¶ 12, 76—77. Despite the publicly-available CAT NSN history showing that NSN 6515-01-521-7976 was assigned to the CAT in 2004—long before the CAT Gen 6 was introduced—Relators repeatedly refer to NSN 6515-01-521-7976 as "unique" to the CAT Gen 6.

Relators allege that "[i]n March 2005, the Army Surgeon General selected the third-generation CAT ('CAT Gen 3') as the primary tourniquet to be issued to soldiers." FAC ¶ 52. As reflected on the Government's publicly available FLIS website,[13] NSN 6515-01-521-7976 was assigned to the CAT on July 6, 2004:

[13] Defense Logistics Agency, the Nation's Combat Logistics Support Agency, *PUB LOG – Public Data* (last visited Feb. 23, 2024), https://www.dla.mil/Information-Operations/Services/Applications/PUB-LOG/. There are several additional steps to access the DLA "Pub Log" entry for the Gen 7 Combat Application Tourniquet (C-A-T) with an NSN of 6515-01-521-7976, requiring the user to download and save a "PUB LOG®" .zip file. The user then accesses a "Publog DVD" folder to install the PubLog database search program. The user then navigates PubLog through the "Search Interactive" icon, which allows the user to run the "FLIS Interact Query" search function. A search for NSN 6515-01-521-7976 (consisting of a four-digit FSC code and a nine-digit NIIN) results in the below Pub Log entry for the CAT Gen 7 with NSN 6515-01-521-7976.



Accordingly, *at least* CAT Gens 3—7 have shared the same NSN; it is *not* "the unique NSN assigned to the CAT Gen 6." FAC ¶ 169.

In 2004, NSN 6515-01-521-7976 was assigned to the CAT as an item of supply. The NSN was not generation-specific, since an item of supply includes: (1) "two or more items that are functionally interchangeable," or "may be substituted for the same purpose and are comparable in terms of use"; and/or (2) "a modification of a normal item of production." Accordingly, assuming that "violating" a "basic principle of Government procurement and logistics" gives rise to a FCA claim, CR did not violate any principle of government procurement by filling orders for NSN 6515-01-521-7976 with CAT Gen 7s.

D. As a matter of law, CR could not cause the CAT Gen 7 to share the same NSN as the CAT Gen 6.

CR could not have "caused the CAT Gen 7 to share the same NSN as the CAT Gen 6." FAC ¶ 19. As Relators acknowledge, the DoD assigns NSNs. FAC p. 16 n.6. NSNs are assigned

by the Government— manufacturers and resellers "*do not have the authority to request an NSN*."[14] NSN assignment is a government procurement function. *See Esper*, 2020 WL 2115447, at *9.

E. Relators do not allege that Section 4.1.1(a) is a condition of payment.

To be actionable fraud under the FCA, "a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a *condition of payment* from the Government." *Wilkins*, 659 F.3d at 309 (emphasis added). Assuming Section 4.1.1(a) is a "basic principle of Government procurement and logistics," and assuming that CR "violated this basic principle of Government procurement and logistics" by filling orders for NSN 6515-01-521-7976 with CAT Gen 7s, Relators have not even alleged that Section 4.1.1(a) is a condition of payment, or that the Government consistently refuses to pay claims based on noncompliance with Section 4.1.1(a). *See United States ex rel. Petratos v. Genentech Inc*., 855 F.3d 481, 489 (3d Cir. 2017).

F. Count One is barred by the public disclosure doctrine.

Further still, Count One is barred by the public disclosure doctrine. The public disclosure bar prevents a relator from pursuing a case and obtaining an award when the fraud allegations have already been subject to a qualifying public disclosure prior to the filing of the qui tam complaint. In particular, the public disclosure bar requires the court to:

> Dismiss an action or claim under this section ... if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

[14] Nsnlookup, *NSN – What is a National Stock Number?* (last visited Feb. 23, 2024), https://www.nsnlookup.com/dla/national-stock-number (emphasis added).

31 U.S.C. § 3730(e)(4). The public disclosure bar, however, contains an exception for Relators who are the "original source of the information" so that even if a public disclosure has occurred, a relator may still proceed if they qualify for this exception. 31 U.S.C. § 3730(e)(4)(A). Both the public disclosure bar and original source exception were amended by Congress in 2010, and these amendments are applicable to this case since the allegations occurred after 2010. *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016).

An original source "means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has stated that to "'materially add[ ]' to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *See United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 306 (3d Cir. 2016). The original source exception is met, therefore, when a relator "contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Id*. at 307; *see also United States ex rel. Ellsworth Assoc., LLP v. CVS Health Corp*., 660 F. Supp. 3d 381, 394–95 (E.D. Pa. 2023).

1. MMQC-16-1284

Relators contend that CR began filling orders for NSN 6515-01-521-7976 with CAT Gen 7s "on or about November 6, 2015." FAC ¶ 72. According to the FAC itself, the U.S. Army

Medical Materiel Agency ("USAMMA") was aware that orders were being filled with CAT Gen 7s no later than March 10, 2016. FAC ¶ 81.

Relators allege that on April 1, 2016, USAMMA "published" a Medical Materiel Quality Control Message ("MMQC-16-1284") "informing other DoD personnel of their findings with respect to the substitution of the CAT Gen 7 for the CAT Gen 6." FAC ¶ 85. When USAMMA published MMQC-16-1284, it specifically noted that CR "continued to use the same part number and NSN for both generations of the tourniquet even though there are significant differences." FAC ¶ 86.

Relators reference MMQC-16-1284 eight times, but they did not attach it as an exhibit to the FAC. MMQC-16-1284 is fatal to Count One.

Specifically, MMQC-16-1284 was "published" on April 1, 2016, and it expressly "informed DOD personnel"[15] that:

1. NAR "has replaced the fielded Generation 6 (Gen6) Tourniquet with the new and different Generation 7 (Gen 7) Tourniquet."

2. CR "continued to use the same part number and NSN for both generations of the tourniquet even though there are significant differences."

3. "There are two different tourniquets on the battlefield with the same part number and NSN."

4. "Service members have been receiving the Gen 7 upon deployment with extremely limited training on how it differs from the Gen 6 which could result in a negative impact to first aid in the field."

5. "To date, there has been no efficacy data supporting equal or improved care for Gen 7. Recommendations from the Committee on Tactical Combat Casualty Care (CoTCCC) are unclear as to the use of Gen 7."

6. "Unable to find valid test and evaluation information on the Gen 7 tourniquet."

7. "The Gen 7 replaced the Gen 6 November 2015."

[15] FAC ¶ 86.

8. "USAMMA was unaware of the change by manufacturer or distributer prior to 10 March 2016." [16]

These are *the exact* allegations underlying Count One, and they were disclosed *by and to* the Government three years before Relators' April 10, 2019 meeting with the FBI, and five years before Relators alleged Count One in these proceedings.

MMQC-16-1284 further stated that "[t]he Army Institute of Surgical Research *did have knowledge* of [the CAT Gen 7]." (Emphasis added). And MMQC-16-1284 directly undermines Relators' allegation that "the CAT Gen 6 and CAT Gen 7 are *nearly indistinguishable* from one another except upon close inspection, especially because the CAT Gen 7 is *packaged in a way that conceals most of its distinguishing features*." FAC ¶ 63 (emphasis added). According to MMQC-16-1284, the CAT Gen 6 and CAT Gen 7 are *easily* distinguishable, even "through [the] manufacturer's packaging":

> "Generation 6 tourniquets have a white Velcro strap. The Generation 7 tourniquet has a grey Velcro strap; NSN (6515-01-521-7976); Lot number and *'G7' are visible through manufacturer's packaging*." (Emphasis added).
>
> Notably, in response to this information, USAMMA did *not*:
>
> - provide that any kit containing the CAT Gen 7 must be canceled and an appropriate kit procured;
> - direct Army units to work with the USAMMA and DLA to stop the procurement of kits containing the CAT Gen 7; or
> - state that kits containing the CAT Gen 7 "have a tourniquet in them that is not approved for Army use or procurement."

As Relators well know, USAMMA could have—and knew how to—make such directives as to the CAT Gen 7 in MMQC-16-1284, if it was material and had USAMMA chosen to do so. In fact,

[16] Exhibit 3.

on September 19, 2018, USAMMA made these very directives in another MMQC as to R*elators' own competing tourniquet*, the TMT.

As referenced in the Factual Background, on September 19, 2018—*over two years after MMQC-16-1284*—USAMMA issued MMQC-18-2324, "inform[ing] all Army units that *the Combat Application Tourniquet (CAT) is the chosen tourniquet for the U.S. Army* in order to ensure our soldiers receive the best possible medical care." *Esper*, 2020 WL 2115447, at *2 (emphasis added). MMQC-18-2324 stated: "The U.S. Army has completed extensive testing based on defined requirements to determine the extremity tourniquet which best meets the needs of the warfighter. *The combat application tourniquet (cat) has met or exceeded all defined requirements, was the superior performer, and was reaffirmed as the chosen extremity tourniquet*." *Id*. (emphasis added).

MMQC-18-2324 further provided that "[a]ny resupply kit previously procured *that does not have the [CAT]* must be canceled and the appropriate resupply kit procured, due to the inherent safety risk of an unauthorized tourniquet." *Id*., at *3 (emphasis added). MMQC-18-2324 directed Army units to work with the USAMMA and the DLA to stop the procurement of two specific first aid kits identified by their NSNs, both of which were manufactured by Relators' company Combat Medical and contained the TMT. *Id*. MMQC 18-2324 stated that these kits "have a tourniquet in them that is not approved for Army use or procurement." *Id*. Combat Medical alleged that because of MMQC 18-2324, TMT's NSN was canceled, and that without an active NSN, Combat Medical was effectively barred from selling the TMT to any DoD purchaser. *Id*.[17]

[17] On May 4, 2020, the court dismissed Combat Medical's claims for want of jurisdiction, holding that Combat Medical's claims had been brought "in connection with a procurement or proposed procurement." *Combat Med., LLC v. Esper*, No. 1:19-CV-1609, 2020 WL 2115447, *6 (E.D. Va. May 4, 2020). Therefore, Combat Medical's claims were within the exclusive jurisdiction of the Court of Federal Claims. *Id*. Relators subsequently brought this *qui tam* action, in which the Government declined to intervene.

But unlike the MMQC in *Esper*, USAMMA did not make such directives as to the CAT Gen 7 two years earlier in MMQC-16-1284. Rather, USAMMA's "Disposition/Instructions" in MMQC-16-1284 were as follows: "As the manufacturer of the C-A-T has released multiple versions of the tourniquet under the same National Stock Number (NSN) and part number, users must read and follow the instructions for use associated with every tourniquet to ensure familiarity with the type of tourniquet users may actually have in their possession."[18] Rather than cancelling or assigning a different NSN to the CAT Gen 7, USAMMA simply instructed users to make sure which generation of the CAT they had, and to read the applicable instructions.

The FAC fails to allege facts which could plausibly show that Relators' NSN-based claims meet the FCA's materiality requirement. Even if Section 4.1.1(a) could be considered a regulatory requirement, and even if filling orders for NSN 6515-01-521-7976 with CAT Gen 7s could be considered regulatory noncompliance, regulatory noncompliance, without more, is not material. *See Alejandro*, 2022 WL 294548, at *5 ("Although 42 C.F.R. § 455.440 requires claims for payment to contain the NPI of the 'professional who ordered or referred such items or services,' Defendants' regulatory noncompliance, without more, is not material."). Relators do not allege any facts to show any of the CAT Gen 7-filled orders would not have been paid if the CAT Gen 7 had been assigned another NSN. *See id*. ("She does not allege any facts to show any of the incorrectly coded claims would not have been paid if the correct optometrist's NPI number had been used instead."). Nothing in the FAC would permit an inference that "Congress intended conduct such as this to morph into an actionable fraud against the government." *United States ex rel. Spay v. CVS Caremark Corp*., 875 F.3d 746, 765 (3d Cir. 2017). In the absence of allegations that the Government paid for services that were not provided, filling orders for NSN 6515-01-521-

[18] Exhibit 3.

7976 with CAT Gen 7s did not improperly "influenc[e] the 'payment or receipt of money'" for those claims. *See Alejandro*, 2022 WL 294548, at *5.

2. The Crown, Aerotech News, and Army Times Articles

In addition to being "published" in MMQC-16-1284, the allegations underlying Count One were disclosed in an October 12, 2016 article found on "army.mil," entitled "Here are the details on the new combat tourniquet" (the "Crown Article").[19] The Crown Article discloses that the "[m]akers of the Combat Application Tourniquet™ have updated the design of the widely used tourniquet," and that "[t]he update has resulted in two different versions of the tourniquet currently in use in the field, though both have the same national stock number (NSN 6515-01-521-7976)."

The Crown Article goes on to describe that "[t]he update version of the CAT, 'Generation 7,' features a single-routing buckle through which Soldiers feed the tourniquet belt before tightening it with the windlass (a textured black rod)," while "[t]he 'Generation 6' CAT model has two slots on the buckle and could be used to either double-route (buddy care) or single-route (self-care) the belt." The Crown Article notes that "[w]hile the updated CAT single-slot buckle is designed for faster and easier application, the Army emphasizes that *both models are effective*." (Emphasis added).

The Crown Article states that "[b]oth have been tested by the Army Medical Research Materiel Command's Institute of Surgical Research and the Navy," and that "Army medics are now trained on both versions." As for appearance, the Crown Article notes that "the two generations differ in the color of the fastener strap. The fastener strap on the new model is gray, compared to a white strap on the older model." And contrary to Relators' allegations, "the new

[19] Ellen Crown, U.S. ARMY Medical Material Agency Public Affairs, *Here are the details on the new combat tourniquet*, (Oct. 12, 2016), https://www.army.mil/article/176507/here_are_the_details_on_the_new_combat_tourniquet.

model's lot number and *'G7' are visible on the device and through the manufacturer's packaging*." (Emphasis added).

The same disclosures were made in the media on October 12, 2016, in the Aerotech News (the "Aerotech News Article")[20] and on October 16, 2016, on "armytimes.com" (the "Army Times Article").[21] Notably, the Army Times Article characterized the CAT as "getting an upgrade," and that according to "the Army Medical Materiel Agency" the "Generation 7 Combat Application Tourniquet will soon be coming to an Individual First Aid Kit near you." The Army Times Article advised that "[t]he older version - Generation 6 - will continue to be fielded, but soldiers should familiarize themselves with both."

3. The Final JOEFT Test Report

Relators reference the JOEFT tests 17 times, including "the Phase III JOEFT tests." FAC ¶¶ 53, 89. But Relators did not attach them as exhibits to the FAC.[22]

The September 3, 2017 final JOEFT test report described "***Equipment Under Test***" as "*Combat Application Tourniquet® (CAT; Generation 7; Composite Resources, Rock Hill, SC)*."[23] The final JOEFT test report noted that "several participants who were familiar *with the earlier generations of the CAT* noted that they felt the CAT had improved."[24] More specifically:

> Some participants familiar with *previous generation CAT designs* commented that they preferred the new single-routed buckle over the previous design, which used a

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[20] AEROTECHNEWS, *Here are the details on the new combat tourniquet* (Oct. 12, 2016), https://www.aerotechnews.com/blog/2016/10/12/here-are-the-details-on-the-new-combat-tourniquet/.

[21] Matthew L. Schehl, ArmyTimes, GearScout, *Army, Marines field next-generation tourniquet* (Oct. 16, 2016), https://www.armytimes.com/off-duty/gearscout/2016/10/16/army-marines-field-next-generation-tourniquet/.

[22] Similarly, in *Esper*, Relators failed to attach the final JOEFT test report to the complaint. *Combat Med., LLC v. Esper*, No. 1:19-CV-1609, 2020 WL 2115447, at *4 n.5 (E.D. Va. May 4, 2020). However, the court reasoned that the complaint referenced the final JOEFT test report four times, and neither party disputed the report's authenticity. *Id*. Accordingly, the court concluded that "the final JOEFT test report may be considered in adjudicating defendants' motion to dismiss." *Id*.

[23] Exhibit 1 at 10 (emphasis original).

[24] *Id*. at 28 (emphasis added).

> double-routed slip lock design. These participants felt the single-routed buckle saved time during two-handed leg applications and simplified the design.[25]

The final JOEFT test report directly acknowledged that "the Generation 7 CAT, which was evaluated in this study, had not been widely fielded at the time of data collection," but that "many of the participants were *familiar with the earlier generations*, which feature *the same general design concept*."[26]

Importantly, the final JOEFT test report undermines the plausibility of Relators' claims that "the CAT Gen 7 has a number of design flaws that create safety risks and operational difficulties." FAC ¶ 90. Under "Results," the final JOEFT test report stated as follows:

> Of the three tourniquet designs, the CAT [Gen 7] achieved the highest combined success rate across arm and leg applications.… The CAT [Gen 7] had the shortest arm application time … and was significantly faster … than the TMT.… The CAT [Gen 7] also had the shortest leg application time … and was significantly faster … than the … TMT.… The CAT [Gen 7] was often ranked the preferred tourniquet design for arm.… The CAT [Gen 7] also ranked most preferred for the leg.…[27]

The final JOEFT test report establishes that the Government was aware of the CAT Gen 7 and its previous designs and generations, and clearly distinguished them from one another. And it renders implausible Relators' characterization of "DoD's recognition that the CAT Gen 7 is unsafe and prone to failure." FAC ¶ 69. "DoD's procurement experts" have been well "alerted" to the CAT Gen 7 for eight years now and—following the final JOEFT test report in September 2017—have expressly "reaffirmed" the CAT Gen 7 as "the chosen extremity tourniquet."

"The materiality standard is demanding. The False Claims Act is not 'an all-purpose anti-fraud statute,' ... or a vehicle for punishing garden-variety breaches of contract or regulatory

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[25] *Id*. at 29 (emphasis added).
[26] *Id*. at 35 (emphasis added).
[27] *Id*. at 5. According to the *Esper* court, "the final JOEFT test report . . . stated that (i) the CAT achieved the highest combined success rate across arm and leg applications, (ii) the CAT had the shortest application times, and (iii) the CAT was ranked as the most preferred tourniquet design by the test subjects." *Combat Med., LLC v. Esper*, No. 1:19-CV-1609, 2020 WL 2115447, at *2 (E.D. Va. May 4, 2020).

violations." *Escobar*, 579 U.S. at 194 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). It is not the Court's job to use "the FCA to enforce regulatory provisions that the regulatory agencies themselves have chosen either [to] not enforce or to enforce more delicately." *Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 320 (E.D. Pa. 2017). Here, the DoD has chosen to reaffirm the CAT Gen 7 as the chosen extremity tourniquet, and Relators have failed to allege facts which could plausibly show that their NSN-base claims meet the FCA's materiality requirement.

4. MMQC-16-1284; the Crown, Aerotech News, and Army Times articles; and final JOEFT test report are properly before the Court.

Courts may consider "documents that are attached to or submitted with the complaint, and any matters incorporated by reference or integral to the [complaint], items subject to judicial notice, matters of public record, orders, and items appearing in the record of the case" in granting a motion to dismiss. *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006); *see also Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (on motion to dismiss, consideration may be given to "the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents"). The Third Circuit has explained that "[t]he rationale underlying this [rule] is that the primary problem raised by looking to documents outside the complaint [is] lack of notice to the plaintiff," and that this problem "is dissipated where the plaintiff has actual notice and has relied upon these documents in framing the complaint." *Corman v. Nationwide Life Ins. Co.*, 396 F. Supp. 3d 530, 535–36 (E.D. Pa. 2019) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

MMQC-16-1284; the Crown, Aerotech News, and Army Times articles; and final JOEFT test report are undisputedly authentic. CR retrieved the final JOEFT test report from the PACER

records for the *Esper* case, where Relators themselves had attached it as an exhibit to Combat Medical's motion for a preliminary injunction. *See Corman v. Nationwide Life Ins. Co*., 396 F. Supp. 3d 530, 536 (E.D. Pa. 2019).

Both MMQC-16-1284 and the final JOEFT test report are "integral to the complaint." *Buck*, 452 F.3d at 260. The "integral" criterion is met where "the claims in the complaint are 'based' on an extrinsic document." *Burlington Coat Factory*, 114 F.3d at 1426. The principal support for Count One is MMQC-16-1284, *see* FAC Section II.c, and thus it is sufficiently "integral" to the Amended Complaint that it may be considered here. *See Corman v. Nationwide Life Ins. Co*., 396 F. Supp. 3d 530, 536 (E.D. Pa. 2019).

Moreover, Relators were on notice that these documents were central to their claims and that they could be relied upon in resolving the motion to dismiss. The FAC quotes MMQC-16-1284 extensively and makes repeated and extensive references to both MMQC-16-1284 to the JOEFT tests, making plain that Relators had notice that those documents could and would be relied upon in resolving this motion to dismiss. Therefore, MMQC-16-1284 and the final JOEFT test report are appropriately considered in resolving this motion to dismiss. *See id*. at 536–37.[28]

Further still, MMQC-16-1284 is excerpted and otherwise described in the FAC. These excerpts and descriptions are part of the factual allegations of the FAC, and therefore they may be considered in resolving the pending motion. *See id*. at 537.

Because notice to the plaintiff is the principal reason for which courts decline to look beyond the complaint, the consideration of documents upon which CR relies does not implicate this rationale. *Id*. Indeed, failure to consider such documents would raise the countervailing concern that "a plaintiff with a legally deficient claim could survive a motion to dismiss simply by

[28] These documents are referenced so frequently and relied on so heavily, their absence as exhibits is conspicuous.

failing to attach a dispositive document on which it relied." *Pension Benefit Guar. Corp*., 998 F.2d at 1196; *see also Hughes v. United Parcel Serv., Inc*., 639 Fed. Appx. 99, 103 (3d Cir. 2016).

5. Relators have failed to adequately plead the original source exception to the public disclosure bar.

Relators vaguely gesture toward the original source exception:

> Plaintiff-Relators are the original sources of the information contained in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4). Plaintiff-Relaters have direct and independent knowledge of the information contained in this Complaint and have voluntarily provided that information to the Government.

FAC ¶ 12. That is the sum and substance of Relators' original source pleadings. Relators do not even attempt to plead any additional information to that which was publicly disclosed so as to improve its quality. Relators do not plead any additional information—distinct from what was publicly disclosed—that adds in any significant way to the essential factual background.

Relators are not original sources of their fraud allegations in Count One. Therefore, Count One is barred by the public disclosure doctrine.

II. Count Two: "False Certification of Compliance with Berry Amendment and TAA"

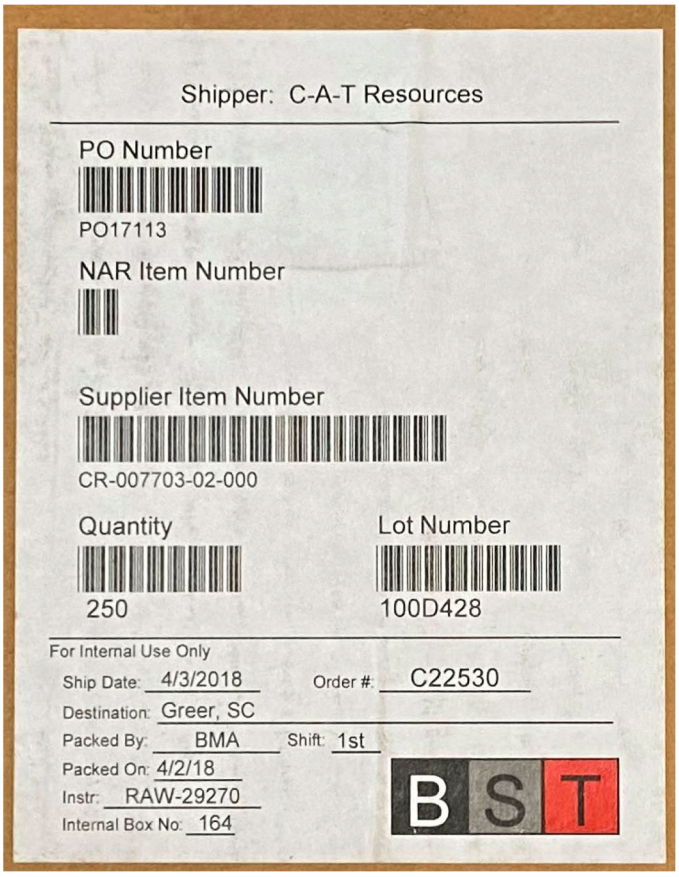
The only "facts" alleged against CR as to Count Two are: (1) the "Fort Bragg Box," (2) the "Lewis McChord Box," and (3) "publicly available video footage first aired in March 2020" allegedly showing that CAT Resources' "manufacturing facilities are not sufficient to produce CATs at the rate Defendants claim, particularly given its lack of automated manufacturing equipment." FAC ¶¶ 116—50.

A. The shipping labels referenced in the FAC render Relators' hyper-conspiratorial allegations in Count Two implausible, if not impossible.

The FAC's allegations as to the Fort Bragg and Lewis McChord Boxes are insufficient to establish a plausible ground for relief. Relators characterize "shipping labels" as "bear[ing]" a Chinese "Customs Registration" number and a "'BMA' mark," which—based on Relators'

"significant knowledge of Chinese and Bahamian customs and shipping practices"—"is an acronym for referring to the Bahamas Maritime Authority." FAC ¶¶ 119, 122, 132. According to Relators, this so-called "mark" was "applied at the Freeport Container Port ('FCP'), a port located in Freeport, a city on the island of Grand Bahama in the Bahamas." FAC ¶ 122.

Relators did not include images of the labels referenced in the FAC. Based on the characterizations in the FAC, one might assume that "CR-0007703-02-000" and "BMA" were stenciled on the boxes, or had some other indicia of having been placed there by some third-party acting in an official capacity. Following the Rule 16 Conference, CR requested—and Relators provided—pictures of the shipping labels referenced in the FAC:



Based on the "Supplier Item Number's" prefix "CR" and "Packed by BMA" on CR's shipping label, Relators' theory is that fully manufactured CATs from China were repackaged in

the Bahamas. According to Relators, CR has "gone to great lengths to *disguise* the Chinese origin of these tourniquets using their convoluted shipping and repackaging scheme to deceive the Government into accepting Chinese-made tourniquets." FAC ¶ 151 (emphasis added).

Relators' theory is not plausible. Relators' pictures of the Fort Bragg and Lewis McChord boxes show that the containers themselves were manufactured in "Charlotte, NC":

According to Relators' hyper-conspiratorial theory, NAR or CR (it is unclear whom) apparently shipped these North Carolina-made boxes to China or the Freeport Container Port (it is unclear which) to be packed with Chinese-made CATs (which, since Relators saw two minutes of newscast footage showing CR employees making COVID masks by hand, could only have been made in China) and then shipped back to South Carolina and on to North Carolina—*after labelling those same boxes with incriminating evidence of Chinese origin ("CR") and Bahamian packaging ("BMA")*. In other words, rather than "disguise" the tourniquets' Chinese origin, CR shipped the

North Carolina-manufactured boxes to Freeport, where they then had the boxes marked with labels displaying their Chinese origin. That is not a reasonable inference to draw and thus fails to meet the plausibility standard. It is not plausible that in a scheme to deceive the Government of the Chinese origin of the CAT, CR had the tourniquets repackaged in the Bahamas with a label clearly indicating Chinese origin.

Further, it is not possible—much less plausible—that "CR" on CR's shipping label signals a Chinese "Customs Registration" number. The Court can take judicial notice[29] of the fact that Customs Registration numbers have ten digits,[30] while "CR-007703-02-000" has eleven. Thus, it is much more likely that "CR-007703-02-000" is what the label says it is: CR's "Supplier Item Number." Likewise, it is much more likely that "CR" stands for C-A-T Resources, not "Customs Registration."[31] Typing "CR-007703-02-000" into a search engine browser demonstrates that the number is associated with the CAT, not a Chinese importer or exporter. *See United States ex rel. Bergman v. Abbot Lab'ys*, 995 F. Supp. 2d 357, 364 (E.D. Pa. 2014) ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'").

Similarly, "BMA" is equally consistent with an individual's initials—for example, Benjamin "Ben" M. Adair, a CR employee since September 2016, and who may have "packed"

[29] When ruling on a motion to dismiss, a court may look beyond the pleadings at "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Federal Rule of Evidence 201(b) permits a court to take judicial notice of a fact not subject to reasonable dispute because it: "(1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); *United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 536 (E.D. Pa. 2022).

[30] CSIWiki, The CSI Help Center & Knowledgebase, *What is a CR Number? (Last Update on Jan. 24, 2023)*, https://ecolorworld.com/wiki/cr-number/.

[31] CR was initially struck by the fact that Relators chose to assign C-A-T Resources, LLC the acronym "CATR" in the FAC, rather than "CR." Upon further consideration, perhaps Relators wanted to avoid an acronym that would—on its face—undermine Relators' "Customs Registration" allegation.

the Fort Bragg Box "1st" shift, and who may have packed the Lewis McChord Box in South Carolina, with CATs made in South Carolina.

B. Relators' "insufficient manufacturing capacity" allegations are barred by the public disclosure doctrine.

Finally, like Count One, Relators' "insufficient manufacturing capacity" allegations are based entirely on "publicly available video footage first aired in March 2020," and thus barred by the public disclosure doctrine. FAC ¶ 148. And as in Count One, Relators did not even attempt to plead any additional information to that which was publicly disclosed so as to improve its quality. Relators do not plead any additional information—distinct from what was publicly disclosed—that adds in any significant way to the essential factual background. Count Two should be dismissed.

CONCLUSION

For the foregoing reasons, CR requests that the Court grant this motion and dismiss the First Amended Complaint. CR further requests that the Court order Relators to reimburse CR for its fees and costs under 31 U.S.C. §3730(d)(4).

This 23rd day of February, 2024

Respectfully submitted,

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